Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Re-evaluation Note REV2017-02

Special Review Decision: Simazine

(publié aussi en français)

10 February 2017

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0630 (print)
1925-0649 (online)

Catalogue number: H113-5/2017-2E (print version)
H113-5/2017-2E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2017

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Special Review Decision

Pursuant to subsection 17(2) of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA) conducted a special review of pest control products containing simazine based on the decisions taken by Norway in 1998 and by the European Commission in 2004 to prohibit all uses of simazine due to environmental concerns. The PMRA evaluated the aspects of concern that prompted the special review in accordance with subsection 18(4) of the *Pest Control Products Act*. The proposed special review decision was published for consultation in the Re-evaluation Note REV2016-09, *Special Review of Simazine: Proposed Decision for Consultation*, and it outlines the Agency's proposed decision and the reasons for it.

Comments received during the consultation process were taken into consideration in making this final special review decision, and they did not result in changes to the proposed regulatory decision as described in REV2016-09. Therefore, the PMRA, under the authority of the *Pest Control Products Act*, is confirming the current registration of pest control products containing simazine in Canada. Appendix I summarizes the comments received and provides the PMRA's response to these comments.

Regulatory Directive DIR2014-01, *Approach to Special Reviews*, presents the details of the PMRA's special review approach.

Other Information

Any person may file a notice of objection[1] regarding this decision on simazine within 60 days from the date of publication of this special review decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website, Request a Reconsideration of Decision, or contact the PMRA's Pest Management Information Service.

[1] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

The PMRA received comments from stakeholders in response to Re-evaluation Note REV2016-09, *Special Review of Simazine: Proposed Decision for Consultation*. The PMRA summarized the comments related to this special review and provides responses below.

1.0 Scope of the Special Review of Simazine

1.1 Comment on the aspect of concern for the special review

A special review conducted pursuant to subsection 17(2) of the *Pest Control Products Act* should consider new information or emerging issues related to health and environmental risks of the subject pest control product, in particular data and studies that may not have been available to, or previously considered by the PMRA. The special review of simazine has not addressed other environment and human health issues including ecological effects other than risk to algae, health effects from simazine use by farmers, farm workers, pesticide applicators, farming communities and the risk to consumers, including those whose drinking water comes from surface water sources.

PMRA Response:

When a special review is initiated under subsection 17(2), the PMRA carries out an analysis of the Organization for Economic Cooperation and Development member country decision to identify the aspect(s) of concern related to the pest control products. For simazine, the aspects of concern that prompted the special review are (1) related to the persistence, mobility and the potential for simazine and its chlorinated transformation products to leach to groundwater and (2) toxicity to algae. As described in Regulatory Directive DIR2014-01, *Approach to Special Reviews*, the PMRA special review evaluation is targeted to address only the aspect(s) of concern related to the pest control product that prompted the special review.

The PMRA has previously implemented mitigation measures to protect workers, surface water used for drinking water and non-target terrestrial and aquatic habitats that may contain sensitive species. Refer to the Re-evaluation Decision RVD2010-01, *Re-evaluation Decision Simazine* for more information.

1.2 Comment on individual products included in the special review

The proposed special review decision of simazine does not examine individual end-use pest control products containing simazine as required by the Act. Simazine is found in some pest control products with other related triazines and chemical preservatives. The entire pest control product should be considered, including all the active ingredients and coformulants.

PMRA Response:

Under the *Pest Control Products Act*, a special review of all registered pest control products containing the active ingredient in question is required. Therefore, as part of this special review, the PMRA considered all registered pest control products (technical and end-use products) that

contain simazine, and the special review decision is applicable to all registered products. A list of the five products containing simazine under special review was provided in Appendix I of REV2016-09. When assessing the potential leaching to groundwater, the PMRA considered the environmental chemistry and fate information from laboratory, field and monitoring studies, and reviewed the risk-reduction measures included on all product labels related to the aspect of concern. While the laboratory studies in general are carried out with technical active ingredients, the field studies were conducted with end-use products containing the active ingredient under actual conditions of use in the field. Additionally, the monitoring data gives an indication of the fate of the active ingredient when used as a formulated product under actual use scenarios.

2.0 Science Evaluation

2.1 Comment on the levels of simazine in groundwater

Simazine has been detected in 13% of groundwater samples in the US and Canada. The maximum level detected in Canada is 1.74 µg/L, which is below the Canadian drinking water guideline of 10 µg/L, but above the level of 0.1 µg/L used by the EU to trigger a ban. The proposed special review decision lacks precaution as it could result in even more contamination of groundwater in Canada with simazine and simazine breakdown products at levels above that considered safe in the EU. Canadians deserve the same level of protection from the harmful effects of pesticides and given the evidence of simazine groundwater contamination in Canada, a new review is necessary to fulfil the requirements of the Act and the result of that reassessment should be a ban.

PMRA Response:

The European Union relies on a level of 0.1 µg/L as the maximum acceptable concentration for an individual pesticide in groundwater. The 0.1 µg/L threshold is a legislated, rather than risk-based, value that applies to all pesticides regardless of their toxicity to humans. Conversely, the PMRA follows a risk-based scientific approach in determining the risk to human health from pesticides in drinking water. This approach takes into consideration both the estimated level in drinking water sources (in other words, exposure) and the toxicity of the pesticide (i.e. hazard).

The PMRA has conducted a drinking water risk assessment for simazine and its chlorinated transformation products, and concluded that there are no acute or chronic risks of concern from simazine at the maximum detected concentration in Canadian groundwater monitoring data of 1.74 µg/L.

2.2 Comment on the Canadian drinking water guideline for simazine

Canada's drinking water guideline for simazine (10 µg/L) is higher than the drinking water standard in the US (4 µg/L) and the standard recommended by the World Health Organization (2 µg/L), indicating that Canada's standard is likely outdated.

PMRA Response:

The PMRA has conducted a drinking water risk assessment for simazine and its chlorinated transformation products, and concluded that there are no acute or chronic risks of concern from simazine at the maximum detected concentration in Canadian groundwater monitoring data of 1.74 µg/L. As well as being below Canada's drinking water guideline for simazine of 10 µg/L, this value of 1.74 µg/L is also below the US drinking water standard of 4 µg/L and below the standard recommended by the World Health Organization of 2 µg/L.

2.3 Comment related to cumulative effects

Simazine is not the only pesticide that Canadians are being exposed to through contaminated drinking water sources. Also, simazine is found in some pest control products with other related triazines and their cumulative effects should be considered.

PMRA Response:

The PMRA considers cumulative health effects of pest control products when a common mechanism of toxicity is identified with other pest control products. Health Canada's Science Policy Notice SPN2001-01, Guidance for Identifying Pesticides that have a *Common Mechanism of Toxicity for Human Health Risk Assessment*, describes the steps for identifying mechanisms of toxicity of pesticides that cause a common toxic effect, the types of data needed and their sources, how these data are to be used in reaching conclusions regarding commonality of mechanisms of toxicity, and the criteria Health Canada applies for categorizing pesticides for the purpose of cumulative assessment. The PMRA did consider triazine cumulative effects in REV2016-09 and concluded that cumulative exposure to triazine residues through drinking water sourced by groundwater was not of concern to human health. Based on the analysis, a common mechanism of toxicity has not been identified for simazine and any other pest control products not in the triazine group, nor is simazine considered to produce a metabolite common to other active ingredients not part of the triazine group of products.

It was further noted that an updated cumulative assessment is ongoing as part of the United States Environmental Protection Agency Registration Reviews for simazine. The PMRA will continue to monitor and work with the United States counter parts on cumulative effects associated with simazine.

References

Published Information

PMRA Document Number	Reference
1822195	Canada, 2009. Pest Management Regulatory Agency Proposed Re-evaluation Decision PRVD2009-12, *Simazine*.
1873824	Canada, 2010. Pest Management Regulatory Agency Re-evaluation Decision, RVD2010-01, *Simazine*.
2405939	Canada, 2013. Pest Management Regulatory Agency Re-evaluation Note REV2013-06, Special Review Initiation of 23 Active Ingredients.
2705374	European Commission, 2003. Review report for the active substance simazine finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 October 2003 in support of a decision concerning the non-inclusion of simazine in Annex I of Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance, SANCO/10495/2003-rev. Final, 10 September 2003.
2705373	European Commission, 2004. Commission Decision of 10 March 2004 concerning the non-inclusion of simazine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance. (2004/247/EC).
2705376	Rotterdam Convention, 2001. Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, PIC Circular XIII – June 2001, pp 16-17.
2530821	Rotterdam Convention, 2005. Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, PIC Circular XXI – June 2005, page 30.
1449407	United States, 2006a. United States Environmental Protection Agency RED for Simazine. April 6, 2006.
2705378	United States, 2006b. Simazine: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED). January 12, 2006.
2530822	United States, 2006c. United States Environmental Protection Agency Triazine Cumulative Risk Assessment. March 28, 2006.

PMRA Document Number	Reference
2705377	United States, 2013a. Registration Review – Preliminary Problem Formulation for the Ecological Risk Assessment of Simazine. May 28, 2013. Docket Number EPA-HQ-OPP-2013-0251-0002.
2705375	United States, 2013b. United States Environmental Protection Agency Simazine Final Work Plan. Registration Review Case Number 70. December 2013. Docket Number EPA-HQ-OPP-2013-0251-0029.

Unpublished Information

PMRA Document Number	Reference
2705379	Norway, undated. Form for Notification of Final Regulatory Action to Ban or Severely Restrict a Chemical. Simazine. Norwegian Agricultural Inspection Service.

Additional Information (Environmental Fate & Modelling)

Unpublished Information

PMRA Document Number	Reference
1148059	B. Gold, K. Balu and A. Hofberg, 1973, Hydrolysis of Simazine In An Aqueous Solution. Report No GAAC-73044. Analytical Chemisty Dept, Agriculutural Division, Ciba-Geigy Corp., Greensboro, North Carolina, DACO: 8.2.3.2
1148062	T. D. Yesu, 1989, Photodegradation of [Triazine(U)-^{14}C] Simazine in Aqueous Solution Buffered At pH 7 Under Artificial Sunlight (89040;151-89;11). Ciba-Geigy No. 151-89. ISSI No. 89040. Ciba-Geigy Corporation, Greensboro, North Carolina, DACO: 8.2.3.3.2
1148066	S. P. Cohen, 1993, Aerobic Soil Metabolism of Simazine, performing laboratory: Pittsburgh Environmental Research Laboratory, Inc., University of Pittsburgh Applies Research Center, 3210 William Pitt Way, Pittsburgh, PA 15238, DACO: 8.2.3.4.2

PMRA Document Number	Reference
1148070	H. Ellgehausen, 1985, Degradation of Simazine in aquatic systems, Project No. 024636, Performing laboratory: RCC, Research and Consulting company, Sponsor: CIBA-GEIGY AG, DACO: 8.2.3.5.2
1148067	S. D. Burton, 1993,Aerobic Aquatic Metabolism of ^{14}C-simazine, performing laboratory: Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, Texas 77478, DACO: 8.2.3.5.4
1148069	W. C. Spare, 1987, Anaerobic aquatic metabolism of Simazine. Agrisearch Incorporated Project No. 1230. Ciba-Geigy Corporation, Greensboro,North Carolina, DACO: 8.2.3.5.6
1148064	W. C. Spare, 1989, Adsorption/Desorption of ^{14}C-Simazine, Final report, Performing laboratory: Agrisearch Inc., Study No: Agrisearch 12168, DACO: 8.2.4.2
1148063	C. W. Yu, 1986. Determination of Adsorption/Desorption Constants of Simazine, Final report, Submitted by: Cambridge Analytical Associates, Inc. 1106 Commonwealth Avenue, Boston, MA 02215, Project No: 59-2A, DACO: 8.2.4.2

Additional Information (Water Monitoring)

Published Information

PMRA Document Number	Reference
1307565	I. Giroux, 1995, Contamination de l'eau souterraine par les pesticides et les nitrates dans les régions de culture de pommes de terre, Campagne d'échantillonnage 1991-1992-1993, ministère de l'Environnement et de la Faune, Direction des écosystèmes aquatiques, Envirodoq EN950125, QE-96, DACO: 8.6
1307578	I. Giroux, 1998, Suivi environnemental des pesticides dans des régions de vergers de pommiers, Rapport d'échantillonnage de petits cours d'eau et de l'eau souterraine au Québec en 1994, 1995 et 1996, ministère de l'Environnement et de la Faune, Direction des écosystèmes aquatiques, Envirodoq EM980361, QE-115, DACO: 8.6
1311119	I. Giroux, 2003, Contamination de l'eau souterraine par les pesticides et les nitrates dans les régions en culture de pommes de terre, Campagne d'échantillonnage de 1999-2000-2001, ministère de l'Environnement, Direction du suivi de l'état de l'environnement, Envirodoq ENV/2003/0233, DACO: 8.6

PMRA Document Number	Reference
1311120	I. Giroux, 2003, Annexes: Contamination de l'eau souterraine par les pesticides et les nitrates dans les régions en culture de pommes de terre, Campagne d'échantillonnage de 1999-2000-2001, ministère de l'Environnement, Direction du suivi de l'état de l'environnement, Envirodoq ENV/2003/0233, DACO: 8.6
1311126	G. Somers, B. Raymond and W. Uhlman, 1999, P.E.I. Water Quality Interpretive Report 99. Prepared for Canada-Prince Edward Island Water Annex to the Federal/Provincial Framework Agreement for Environmental Cooperation in Atlantic Canada, DACO: 8.6
1774484	United States Department of Agriculture (USDA), 2008, Pesticide Data Program Annual Summary, Calendar Year 2007, Science and Technology Programs, USDA, DACO: 8.6
1852614	United States Department of Agriculture (USDA), 2009, Pesticide Data Program Annual Summary, Calendar Year 2008, Science and Technology Programs, USDA. December 2009, DACO: 8.6
2102603	I. Giroux and B. Sarrasin, 2011, Pesticides et nitrates dans l'eau souterraine près de cultures de pommes de terre - Échantillonnage dans quelques régions du Québec en 2008 et 2009, ministère du Développement durable, de l'Environnement et des Parcs, Direction du suivi de l'état de l'environnement, Centre d'expertise en analyse environnementale du Québec, ISBN 978-2-550-61396-1. 31 pages + 5 appendices. DACO: 8.6
2170923	D. Moerman and D. Briggins, 1994, Nova Scotia Farm Well Water Quality Assurance Study. Government of Nova Scotia, DACO: 8.6
2170925	Nova Scotia Environment, 2010, Nova Scotia Groundwater Observation Well Network 2010 Report, DACO: 8.6
2312776	United States Department of Agriculture (USDA), 2011, Pesticide Data Program Annual Summary, Calendar Year 2009. Science and Technology Programs, USDA. May 2011, DACO: 8.6
2312778	United States Department of Agriculture (USDA), 2012, Pesticide Data Program Annual Summary, Calendar Year 2010. Science and Technology Programs, USDA. May 2012, DACO: 8.6
2312780	United States Department of Agriculture (USDA), 2013, Pesticide Data Program Annual Summary, Calendar Year 2011. Science and Technology Programs, USDA. February 2013, DACO: 8.6
2397189	Nova Scotia Environment, 2011, Nova Scotia Groundwater Observation Well Network. 2011 Report, DACO: 8.6
2397190	Nova Scotia Environment, 2012, Nova Scotia Groundwater Observation Well Network. 2012 Report, DACO: 8.6
2397195	California Environmental Protection Agency, Department of Pesticide Regulation, 2013, Sampling for Pesticide Residues in California Well Water 2012 Update. Twenty-seventh Annual Report, DACO: 8.6

PMRA Document Number	Reference
2401692	United States Environmental Protection Agency, 2014, Water and sediment monitoring data for simazine (2006 to March 2014) from the US EPA's Storage and Retrieval (STORET) Data Warehouse. Downloaded March 7, 2014. http://iaspub.epa.gov/storpubl/DW_resultcriteria_geo, DACO: 8.6
2401693	United States Geological Survey, 2014, USGS National Water Quality Assessment (NAWQA) program groundwater, surface water and sediment monitoring data for simazine (2006 to March 2014), downloaded March 7, 2014. http://water.usgs.gov/nawqa/, DACO: 8.6
2482501	C. Garretson, 2013, Study Memo 228. Study 182/188 - Summary of Well Network Sampling Results from 1999 through 2012. California Department of Pesticide Regulation. March 11, 2013. Accessed December 12, 2014. http://www.cdpr.ca.gov/docs/emon/pubs/ehapreps/228_study_memo_2013.pdf, DACO: 8.6
2505827	United States Department of Agriculture (USDA), 2012, Pesticide Data Program Annual Summary, Calendar Year 2012, Science and Technology Programs, USDA, DACO: 8.6
2505828	United States Department of Agriculture (USDA), 2013, Pesticide Data Program Annual Summary, Calendar Year 2013, Science and Technology Programs, USDA, DACO: 8.6

Unpublished Information

PMRA Document Number	Reference
1311111	2005, Environment Canada, Unpublished Pesticide Science Fund Annual Report 2004-2005. (Water, Air, Plants, Mammals, Amphibians, Fish and Birds), DACO: 8.6
1311112	2004, Environment Canada, Unpublished national water monitoring data. Pesticide Science Fund (2004), DACO: 8.6
1345590	Ultratrace Detection of Herbicides in Prairie Springs., DACO: 8.6
1345591	Unpublished Groundwater Monitoring Data of Pesticides in the Fraser valley, B.C. (2001), DACO: 8.6
1403269	2006, Environment Canada, Pesticide Science Fund Annual Report 2005-2006, DACO: 8.6

PMRA Document Number	Reference
2171036	2010, Unpublished groundwater monitoring data from Ontario's Provincial Groundwater Monitoring Network. Received September 2011 from the Ontario Ministry of the Environment, DACO: 8.6
2404790	2014, Monitoring data on simazine from the Montana Department of Agriculture, submitted following the PMRA's February 2014 monitoring data request for active ingredients under special review. Data submitted March 14, 2014, DACO: 8.6
2408636	2014, MDDEFP, Monitoring data on simazine in surface water and groundwater submitted following the PMRA's February 2014 monitoring data request for active ingredients under special review. Data submitted March 19, 2014. Banque de données sur la qualité du milieu aquatique (BQMA), Québec, ministère du Développement durable, de l'Environnement, de la Faune et des Parcs. Direction du suivi de l'état de l'environnement, DACO: 8.6
2424920	2014, British Columbia Ministry of Forests, Lands and Natural Resource Operations, Monitoring data for pesticides in groundwater, collected in 2010 from wells in British Columbia. Submitted following the PMRA's April 2014 monitoring data request for active ingredients under special review. Data submitted May 12, 2014, DACO: 8.6
2442754	2014, Alberta Environment and Sustainable Resource Development, Monitoring data on simazine from the Government of Alberta, submitted following the PMRA's February 2014 monitoring data request for active ingredients under special review. Data submitted July 24, 2014, DACO: 8.6
2538228	United States Environmental Protection Agency. 2015. Water monitoring data for desisopropyl atrazine (DIA) (1992-2014) from the US EPA's Storage and Retrieval (STORET) data warehouse. Downloaded May 26, 2015. http://iaspub.epa.gov/storpubl/DW_resultcriteria_geo